

### REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants have added the drawing Figure 17, which is fully supported in the as-filed specification. Claims 50 – 52 and 34 have been objected to since those features which support the limitation “the carrier comprises a ring” which appears in claims 50 – 52 and the limitation “a constriction ring element” which appears in claim 34 did not appear in the as-filed drawings figures. Since Fig. 17 is fully supported in the specification as-filed, withdrawal of the objection to the drawings under 37 CFR § 1.83(a) is respectfully requested.

The specification has been amended to add the brief description of new Fig. 17 at page 15, line 20 and at page 34, lines 5-8.

The paragraphs at page 29, line 28 to page 30, line 22 and at page 33, lines 10-24, have been amended to correct a typographical error that caused “slot 79” to appear as “slit 79.” The correct reference to “slots 79” first appears at page 28, line 1. Thus, no new matter is added by the correction of this inadvertent typographical error.

Also, in the paragraph at page 29, line 28 to page 30, line 22, correction of a typographical error in the word “anchoring” has been made, and reference to specific claims in the present application have been removed.

No new matter is added by these amendments.

Claims 31, 32 and 36 have been rejected under § 112, second paragraph for indefiniteness. The term thought to be indefinite, namely, “first penetrated position” in claim 31 now reads “the first position”, “penetrated” having been deleted. Since the rejection has been overcome, its withdrawal is solicited.

Claims 50 – 52 stand rejected for indefiniteness under § 112, second paragraph. This rejection is traversed. Claim 50 now recites “a carrier ring” which serves to provide the clarity sought for by the Examiner. Since the rejection has been overcome its withdrawal is respectfully requested.

Claims 31-33, 35-37, 49-52 and 54 have been amended. The amendments are fully supported in the as-filed specification.

New claims 56 – 59 have been added and they are fully supported in the specification as filed.

The pending claims are 31-37 and 45-49.

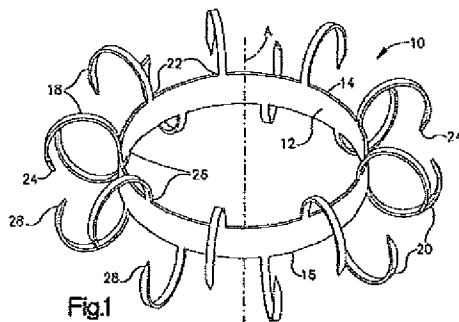
#### **Rejection Under 35 USC §102**

Claims 31 – 37, 44 – 52 and 55 have been rejected under 35 USC §102(e) as being anticipated by Gabbay (US 7,311,730). This rejection is respectfully traversed.

The Examiner indicated that Claim 54 would be allowable if rewritten in independent form. New independent Claim 59 has been added, which contains all of the limitations of Claim 31 and Claim 54.

Further, the first part of claim 54 has been shifted to a separate new Claim 56 and Claim 54 has been amended to depend from new claim 56. Applicant trusts that amended Claim 54 still is allowable.

This patent describes a device for mounting a heart valve inside an annulus. The mounting device is shown in fig 1 without valve and covering textile:



It should be noted that starting from the straight first position, the pins 24/28 of Gabbay bend in a radially outward direction (and not in a radially inward direction as required by claim 31). Thus Gabbay does not disclose pins *moving from a straight first position in a radial inward direction to a second position*.

Further, referring to the sequence of figures 5-7 of Gabbay and the description of these figures, it is also clear that the pins of Gabbay are not and cannot be straight when fully penetrated into the valve annulus tissue. When the cylindrical member 202 is withdrawn from the position shown in figure 5 of Gabbay to the position shown in figure 6 of Gabbay, the lower pins 264 will assume a curved configuration and will pierce the tissue along a correspondingly curved path. When the cylindrical member 202 is further withdrawn from the position shown in figure 6 of Gabbay to the position shown in figure 7 of Gabbay, the upper pins 254 will – upon release from the cylindrical member - immediately assume their curved configuration whilst simultaneously penetrating the tissue. This will cause severe damage of the penetrated tissue as this tissue is ruptured by the pins 254.

With the prosthesis according to claim 31, the anchoring pins are, when fully penetrated into the tissue, initially still straight and axial and start from this straight and axial first position and then move radial inwardly to the second position. In other words, when penetrating the tissue, the anchoring pins of claim 31 are straight and axial. Damage of the tissue by the pins is thus minimal as the pins can be pierced axially into the tissue. Subsequently, when moving radially inward to the second position, the tissue surrounding the ring member of the prosthesis is pressed against the outside of the ring member so that sealing between the tissue and ring member is improved and bypass leakage along the outside of the prosthesis is correspondingly reduced.

Claim 31 thus patentably distinguishes over the teaching of Gabbay. Accordingly, since the Examiner has not established a *prima facie* case of anticipation under §102(e), the rejection has been overcome and should be withdrawn.

Referring to new claim 56, it is further noted that in Gabbay the pins 24/28, 254/264 in fact form the lower and upper flange and that consequently the pins of Gabbay can not be arranged (and are not arranged) between the upper and lower flange. Additionally, according to new claim 56 the pins are, in the straight first position, arranged between the upper and lower flange. Also, this is clearly not the case in Gabbay.

New claim 56 is, therefore, also patentably distinguishable over the teaching of Gabbay. Withdrawal of the rejection is respectfully solicited since a *prima facie* case of anticipation has not been established.

Referring to new claim 57, it is noted that in the straight position of the Gabbay pins, there are no pins extending from any flange towards the other flange. The pins of Gabbay extend in the straight position away from each other, i.e. away from the opposing other flange.

Thus, new claim 57 also patentably distinguishes over the teaching of Gabbay. The rejection under § 102(e) should be withdrawn since *prima facie* anticipation has not been established.

Referring to new claim 58, it is noted that Gabbay does not show or teach an upper flange having slots through which axial fingers extend, which axial fingers serve the purpose of releasing the pins separately from releasing the lower flange to return to its radial position.

New claim 58 therefore also patentably distinguishes over the teaching of Gabbay. Withdrawal of the rejection for failure to establish *prima facie* anticipation by a preponderance of the evidence is solicited.

### **Rejection under 35 USC § 103**

Claim 53 stands rejected as obvious over US 7,311,730 (Gabbay) in view of U.S. Publication 2009/0216115 to Seiler. This rejection is traversed.

According to the Examiner, it would have been obvious to provide a tissue enhancing drug or material to the prosthesis of Gabbay to obtain the claimed invention. As noted above, Gabbay fails to teach or suggest the claimed heart valve prosthesis, thus the combination of Gabbay and Seiler do not render the claims obvious. Since *prima facie* obviousness under § 103(a) has not been established, withdrawal of the rejection is respectfully solicited.

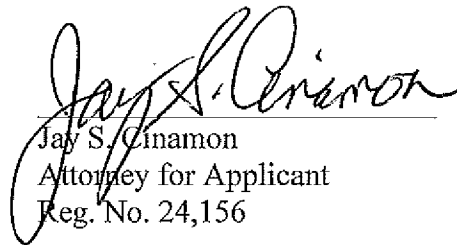
In view of the foregoing amendments and remarks, Applicant believes the claims are in condition for allowance, and a Notice to that effect is respectfully requested.

Please charge any other fees which may be due to our Deposit Account No. 01-0035.

Respectfully submitted,

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